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APPLICATION NO.	· FILING	DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/608,276 06/27/2003		Michael A. Centanni	ST8010US	8508	
22203	7590	11/04/2005		EXAMINER	
KUSNER & JAFFE				SINES, BRIAN J	
HIGHLAND PLACE SUITE 310 6151 WILSON MILLS ROAD HIGHLAND HEIGHTS, OH 44143				ART UNIT	PAPER NUMBER
				1743	

DATE MAILED: 11/04/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

	Application No.	Applicant(s)					
Office Action Comments	10/608,276	CENTANNI, MICHAEL A.					
Office Action Summary	Examiner	Art Unit					
	Brian J. Sines	1743					
The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply							
A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).							
Status							
1) Responsive to communication(s) filed on 9/19/3	200 <u>5</u> .						
	action is non-final.	•					
3)☐ Since this application is in condition for allowan	3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is						
closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.							
Disposition of Claims							
4) Claim(s) 1-7,10-19,22-24,45-54 and 58-60 is/are pending in the application.							
4a) Of the above claim(s) is/are withdrawn from consideration.							
5) Claim(s) is/are allowed.							
6) Claim(s) 1-7,10-19,22-24,45-54 and 58-60 is/are rejected.							
7) Claim(s) is/are objected to.							
8) Claim(s) are subject to restriction and/or	election requirement.	·					
Application Papers							
9) The specification is objected to by the Examiner.							
10) The drawing(s) filed on is/are: a) accepted or b) objected to by the Examiner.							
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).							
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).							
11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.							
Priority under 35 U.S.C. § 119							
12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).							
a) ☐ All b) ☐ Some * c) ☐ None of:							
1. Certified copies of the priority documents have been received.							
2. Certified copies of the priority documents have been received in Application No							
3. Copies of the certified copies of the priority documents have been received in this National Stage							
application from the International Bureau (PCT Rule 17.2(a)).							
* See the attached detailed Office action for a list of the certified copies not received.							
Attachment(s)	•						
1) Notice of References Cited (PTO-892)	(PTO-413)						
2) Notice of Draftsperson's Patent Drawing Review (PTO-948)	Paper No(s)/Mail Da	ate atent Application (PTO-152)					
3) Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date	6) Other:						

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DETAILED ACTION

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

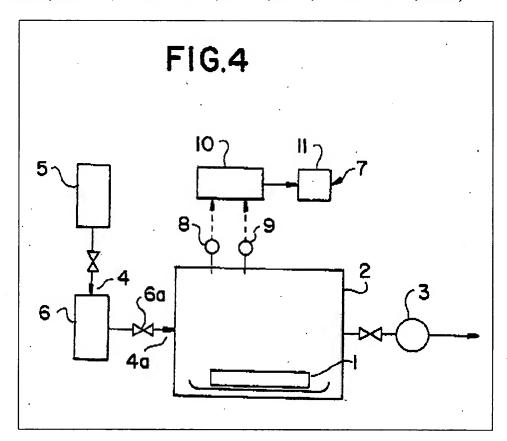
(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 10 - 13, 22 - 24, 45 - 47, 58 and 59 are rejected under 35 U.S.C. 102(b) as being anticipated by Ando et al. (U.S. Pat. No. 5,608,156 A) (hereinafter "Ando").

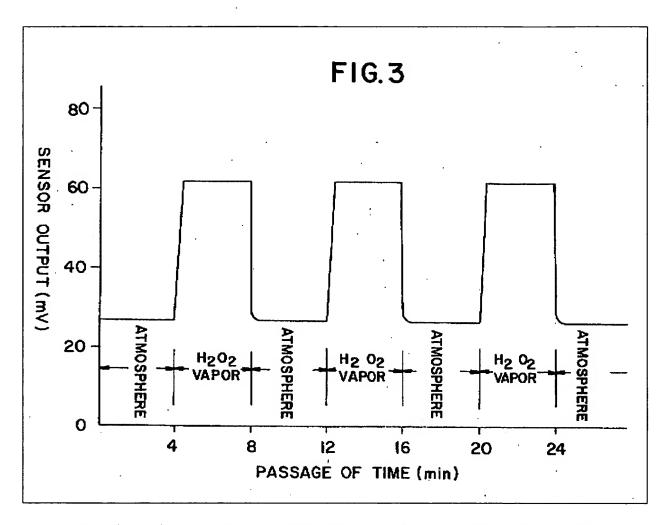
Regarding claim 1, Ando anticipates an apparatus for sensing a concentration of vaporized hydrogen peroxide in a biocontamination deactivation or sterilization process on a real-time basis, comprising: a chamber (treatment vessel 2); a sensing element comprising of an electroactive material (metal oxide semiconductor gas sensor 8 whose electrical conductivity changes in contact with the hydrogen peroxide vapor in the chamber) (see col. 5, lines 36 - 65); and a concentration detection system (e.g., concentration detecting apparatus 7, computing unit 10 & concentration indicator 11) comprising: means for determining a measured value indicative of a change in an electrical property of the electroactive material as a function of time exposure of the electroactive material to the hydrogen peroxide vapor in the chamber, wherein the change in electrical property varies in accordance with a change in concentration of the hydrogen peroxide vapor in the chamber; memory means for storing predetermined data indicative of the electrical property as a function of time exposure of the electroactive material to hydrogen peroxide vapor at known concentrations; and means for determining a concentration of the hydrogen peroxide vapor corresponding to the measured value using the predetermined data

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stored in the memory means (see col. 4, line 55 – col. 11, line 6; figure 4). Ando teaches that the computing unit (10) receives the output signal from the sensor (8), determines a measured value for the sensor response, and the output from the sensor (8) is converted to the concentration of the hydrogen peroxide vapor for indication as a function of time (see figures 2 – 6; col. 5, line 36 – col. 6, line 43). Ando teaches that the computing unit (10) also stores predetermined correction or calibration data (i.e., a conversion rate) (see col. 8, lines 52 – 67). Ando teaches that the concentration indicator (11) uses predetermined data (i.e., a conversion rate) obtained in advance by experiments (see col. 5, line 66 – col. 6, line 43; col. 7, line 62 – col. 8, line 8).



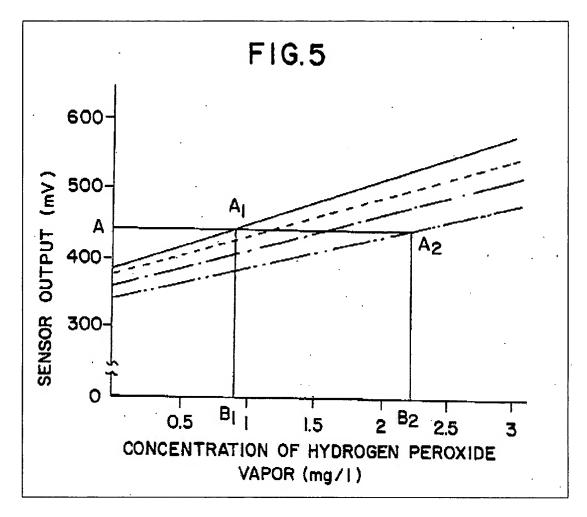
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Regarding claim 10, Ando also teaches that computing unit (10) functions as a data comparison means during operation (see col. 9, line 58 – col. 10, line 31).

Regarding claim 11, Ando teaches that the predetermined correction data incorporates the use of a predetermined conversion rate, which is inherently anticipated to be a slope value (see col. 3, line 66 - col. 4, line 33; col. 5, line 66 - col. 6, line 43; col. 7, line 1 - col. 8, line 33). A slope value for a linear calibration line is mathematically a rate (see figures 2 & 6).

Regarding claim 12, as shown in figure 5, Ando indicates that the computing unit (10) also functions as a means for interpolating and extrapolating data (see col. 9, line 58 – col. 10, line 62).



Regarding claims 13, 22 - 24, 45 - 47, 58 and 59, as discussed above, Ando teaches all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Regarding process or method claims, a prior art device anticipates a claimed process, if the device carries out the process during normal operation (see MPEP $\S 2112.02$).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are

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such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* v. *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

- 1. Determining the scope and contents of the prior art.
- 2. Ascertaining the differences between the prior art and the claims at issue.
- 3. Resolving the level of ordinary skill in the pertinent art.
- 4. Considering objective evidence present in the application indicating obviousness or nonobviousness.
- 1. Claims 2 5, 14 17, 48 52 and 60 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ando et al. (U.S. Pat. No. 5,608,156 A) (hereinafter "Ando") in view of Guiseppi-Elie (U.S. Pat. No. 5,352,574 A) (hereinafter "Guiseppi-Elie").

Regarding claims 2 and 3, Ando does not specifically teach the incorporation of an electroactive polymer, such as polyacetylene, with the sensing element. As discussed above, Ando does teach the use of a metal oxide semiconductor gas sensor for sensing hydrogen peroxide vapor (see col. 5, lines 36 – 65). Guiseppi-Elie does teach a sensing apparatus for determining the concentration of hydrogen peroxide comprising: a sensing element comprising an electroactive material (e.g., a polymeric film comprising polyacetylene deposited on interdigitated grid area A); and a concentration determination means, which is based upon change in electrical conductivity (see col. 6, lines 14 – 28; col. 7, lines 3 – 11; figure 3). Guiseppi-Elie indicates that the disclosed sensing apparatus is suitable for use in sensing gaseous samples (see col. 11, lines 3 – 12). Hence, the two types of sensors disclosed by Ando and Guiseppi-Elie used for determining the concentration of hydrogen peroxide vapor are considered functional equivalents (see MPEP § 2144.06). The Courts have held that an express suggestion to

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substitute one equivalent component or process for another is not necessary to render such a substitution obvious. See *In re Fout*, 675 F.2d 297, 213 USPQ 532 (CCPA 1982). Therefore, it would have been obvious to a person of ordinary skill in the art to incorporate a sensor comprising an electroactive polyacetylene polmer for sensing hydrogen peroxide vapor with the disclosed apparatus.

Regarding claims 4 and 5, Guiseppi-Elie further teaches the incorporation of dopants, such as iodine (see col. 3, lines 1 - 18).

Regarding claim 48, Guiseppi-Elie indicates that the disclosed sensing apparatus can detect bromine (see col. 3, lines 1 - 18).

Regarding claim 60, polyacetylene is well known in the art to be semicrystalline, thus comprising both crystalline and noncrystalline phases, and therefore containing amorphous regions (see MPEP § 2144.03).

Regarding claims 14 – 17, 48 – 52 and 60, as discussed above, Ando in view of Guiseppi-Elie teaches all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the apparatus of Ando and Guiseppi-Elie, as such is the intended operation of that apparatus.

2. Claims 6, 7, 18, 19, 53 and 54 are rejected under 35 U.S.C. 103(a) as being unpatentable over Ando and Guiseppi-Elie Lewis, as applied to the claims above, and further in view of Nahass et al. (U.S. Pat. No. 5,651,922 A) (hereinafter "Nahass").

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Regarding claims 6 and 7, Ando and Guiseppi-Elie do not specifically teach the incorporation of a pitch-based carbon/graphite fiber material. Guiseppi-Elie does teach the incorporation of a bromine dopant (see col. 3, lines 4 – 18). Nahass teaches the incorporation of a pitch-based carbon fiber in the manufacture of conductive polymers in order to modify or increase the conductivity of the conductive polymers to adjust sensitivity of the sensor (see col. 1, lines 15 – 39). The Courts have held that the selection of a known material, which is based upon its suitability for the intended use, is within the ambit of one of ordinary skill in the art. See *In re Leshin*, 125 USPQ 416 (CCPA 1960) (see MPEP § 2144.07). Therefore, it would have been obvious to a person of ordinary skill in the art to provide for the claimed apparatus as recited in the instant claims.

Regarding claims 18, 19 and 53, as discussed above, Ando in view of Guiseppi-Elie and Nahass teaches all of the positively recited structure of the apparatus provided in the claimed method, which merely recites the conventional operation of that apparatus. Therefore, it would have been obvious to a person of ordinary skill in the art to perform the method recited in the instant claims upon the disclosed apparatus, as such is the intended operation of that apparatus.

Response to Arguments

Applicant's arguments with respect to the pending claims have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. The additional cited prior art teaches various sterilization monitoring processes and systems.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Brian J. Sines, Ph.D. whose telephone number is (571) 272-1263. The examiner can normally be reached on Monday - Friday (11 AM - 8 PM EST).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill A. Warden can be reached on (571) 272-1267. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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